IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SYSMEX CORPORATION and SYSMEX AMERICA, INC.,	
Plaintiffs,	C.A. No.: 19-1642-RGA-CJB
	JURY TRIAL DEMANDED
v.	
BECKMAN COULTER, INC.,	[redacted]
Defendant.	**REDACTED PUBLIC VERSION**

SYSMEX CORPORATION AND SYSMEX AMERICA, INC.'S COMBINED OPENING BRIEF IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT AND MOTION TO EXCLUDE CERTAIN OPINIONS OF JOHN W. ROCHE AND MITCHELL B. ROSEN

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Dated: November 30, 2021

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I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs (collectively "Sysmex") filed this patent infringement lawsuit against Defendant ("BCI") on September 3, 2019. (D.I. 1.) Sysmex alleges BCI's DxH Series blood and body fluid analyzers (the "Accused Product") infringe U.S. Patent Nos. 10,401,350 and 10,401,351 (the "'350 patent" and "'351 patent", respectively; the "Asserted Patents" collectively). (*Id.*; Exs. 1-2.) Sysmex has narrowed the claims asserted against the Accused Product to: '350 claims 1, 4, 9, 12, 18-21, 27 and 28 and '351 claims 1, 4, 6, 16-17, 21 and 23-26 (the "Asserted Claims"). (D.I. 368.) Fact and expert discovery are complete.

II. INTRODUCTION

BCI has taken an "everything but the kitchen sink" approach to asserting defenses in this case, including inequitable conduct, anticipation under 35 U.S.C. § 102(b), obviousness under § 103, derivation under § 102(f), and written description, enablement, and indefiniteness under § 112. However, BCI has failed to provide evidence to support many of these defenses, and its experts have resorted to unsupported, conclusory statements. Instead of dropping its unsupported defenses, BCI confirmed in its supplemental invalidity contentions served on October 29, 2021 that it would continue to assert them. As a result, Sysmex was forced to file this present motion seeking summary judgment under *Celotex* based on BCI's failure to present evidence to support its numerous defenses, and to preclude BCI's experts from providing testimony that does not meet the *Daubert* standard.

III. BACKGROUND OF THE TECHNOLOGY AND THE PATENTS IN SUIT

Blood and body fluid samples are measured to help diagnose and treat patients. Body fluid analysis is essential for diagnosing numerous medical conditions in both adults and children such as meningitis, encephalitis, or leukemic cerebrospinal fluid and is also useful for monitoring cancer patients' responses to chemotherapy. (D.I. 133 at Ex. 1, p. 1 (Introduction).)

For many years, body fluid measurements and analysis were performed by manually counting cells in a body fluid sample on a slide under a microscope. This manual procedure was long-considered the gold standard, but it had several disadvantages such as low precision, high cost, delayed results, and the requirement of skilled personnel. (*Id.* at p. 2 (Introduction cont'd).) Eventually, some hematology analyzers, that were designed and FDA approved for blood analysis, were found to measure body fluids with results as accurate as the manual method. (*Id.* at Ex. 2, p. 396.) As a result, some of these hematology analyzers obtained U.S. FDA approval for a measuring body fluids, including Sysmex's XE-2100 in 2004 and BCI's LH-750 in 2003. The approval was known as a body fluid application. (Ex. 3 at SAI-Del00007280 ("The Body Fluid Application adds a quantitative, automated procedure for analyzing cerebrospinal fluid, serous fluid and synovial fluid to the XE-2100 Series, providing enumeration of the WBCs and RBCs").) Sysmex's FDA application demonstrates that blood and body fluid samples were processed in the same way, as no software or product design changes were required for the body fluid application. (*Id.* at SAI-Del00007335 (software documentation has not changed) and SAI-Del00007282 (showing that software changes were not a reason for submission).) BCI confirmed that: "Whether used for either blood or body fluids, these prior art hematology analyzers operated the same way." (D.I. 133 at p. 4; *see also* Ex. 4, 61:4-62:1, 78:6-13 (LH 750 operated in same way for blood and body fluid samples).) However, without a distinct measurement mode for body fluids, these devices were unable to provide an efficient and complete analysis of body fluid cell counts. (D.I. 133 at Ex. 2, pp. 396, 400.)

Sysmex invented and developed the world's first fully automated hematology analyzer, the XE-5000, which could be easily switched between a blood measuring mode and a distinct body fluid measuring mode. (*Id.* at p. 396.) The distinct body fluid measuring mode provided

additional, and different, operations for measuring body fluid samples that were not necessary for blood samples, such as counting and separately displaying separate counts of mono-nucleated cells and poly-nucleated cells in a body fluid sample. (*Id.*; *see also id.* at Ex. 1, pp. 2-3, and Ex. 3 at pp. 673-75.) Sysmex's FDA application makes clear that a major difference between the XE-5000 and the XE-2100 is that XE-5000 had a distinct body fluid mode as compared to the body fluid application found in the XE-2100. (Ex. 5 at SAI-Del00163366.) About two years later, BCI transitioned away from offering its conventional blood hematology analyzer and launched its accused DxH analyzer, which includes a blood measuring mode and a distinct body fluid measuring mode, just like Sysmex's invention. (*See* D.I. 133 at Ex. 4, p. 1-2, 6.)

Sysmex filed several patent applications to protect its innovations, which led to the issuance of the '350 and '351 patents. These patents share the same specification[1] and describe a sample analyzer having a plurality of detectors for sensing cells in a blood sample in a blood measuring mode and in a body fluid sample in a body fluid measuring mode. (Ex. 1, Abstract.) The blood measuring mode and the body fluid measuring mode are separate measurement modes that must be selected by a user. (Ex. 1, Figs. 7-8, and 9:12-46, 10:53-11:4.) The blood measuring and body fluid measuring modes comprise different operations as illustrated in Fig. 7 and different display screens as shown in Figs. 13 and 14. (*Id.*, Figs. 7, 13-14, and 8:56-13:18.)

IV. BCI'S INEQUITABLE CONDUCT CLAIMS SHOULD BE DISMISSED

A. Summary of the Argument

BCI's inequitable conduct counterclaim and affirmative defense are based on allegations that attorney Horie and inventors Nagai and Narisada allegedly knew about material prior art references in 2004-05 and withheld them from the PTO during prosecution of the Asserted Patents

[1] All citations to the patent specification will be from the '350 patent unless otherwise specified.

fourteen years later in 2018-19 with deceptive intent. Importantly, the law requires that knowledge of the alleged withheld material prior art and deceptive intent be contemporaneous with the prosecution of the asserted patents. Despite having a full discovery record, BCI has no evidence from which the Court can conclude that the single most reasonable inference is that Horie, Nagai and Narisada knew of the allegedly withheld information during prosecution and withheld it from the PTO with an intent to deceive. Instead, a more reasonable inference is that they did not have knowledge of the alleged withheld references during the prosecution of the Asserted Patents and did not have an intent to deceive the PTO.

B. Undisputed Material Facts Regarding Inequitable Conduct

The '350 and '351 patents were filed on December 18, 2018 and March 25, 2019, respectively, and both issued on September 3, 2019. (Exs. 1-2.) BCI alleges that patent attorney Tadashi Horie and inventors Takaaki Nagai and Noriyuki Narisada allegedly withheld the following: (i) the XE-2100 with Body Fluid Application, (ii) the XE-2100 Main Unit Manual and (iii) the XE-2100 IPU Manual references (collectively, the "Alleged Withheld References"). (*See* D.I. 302, counterclaim ¶¶ 12-13.) BCI has no evidence that Horie, Nagai, or Narisada had the requisite knowledge of the references during the prosecution of the '350 and '351 patents or a specific intent to deceive the PTO.

Horie did not know about the Alleged Withheld References during the prosecution of the '350 and '351 patents. (Ex. 6, 109:19-110:4, 104:8-106:10, 131:19-133:24; Ex. 7 at 6-7.) During his deposition, Horie specifically testified that he has no recollection of ever having heard of the XE-2100 analyzer with Body Fluid application prior to the filing of this lawsuit on September 3, 2019 (which occurred on the same date that the Asserted Patents issued), and the first time he saw the XE-2100 Main Unit Manual and the XE-2100 IPU Manual was ***after*** this lawsuit was filed. (Ex. 6, 109:19-110:4, 104:8-106:10, 131:19-133:24.)

BCI Objects to Sysmex's Redactions

During prosecution, Horie submitted to the PTO material from BCI's challenge to the validity of the European counterpart to the Asserted Patents, including (i), an article entitled "performance Evaluation of the Application of Body Fluids on Sysmex XE-2100 Series Automated Hematology Analyzer" (D.I. 311 at 2-3, n.4 and Ex. A ("Kresie"), (ii) a 255-page XE-2100 IPU Manual that described the operation of the XE-2100 (*Id.* at Ex. B ("D32")), (iii) BCI's September 12, 2018 EPO Submission that included BCI's invalidity arguments that characterized the 255-page XE-2100 IPU Manual as being "highly relevant" (*Id.* at Ex. C), and (iv) BCI's June 1, 2018 EPO submission that included further BCI invalidity arguments (*Id.* at Ex. D).[2] (Exs. 1-2 (highlighted publications under References Cited).)

Nagai did not know about the Alleged Withheld References during the prosecution of the '350 and '351 patents. (Ex. 8, 39:20-40:4, 41:4-11, 42:7-43:2, 78:8-23, 81:25-82:7; Ex. 7 at 6-7.) Nagai testified that [redacted]. (Ex. 8, 39:20-40:4, 41:4-11, 42:7-43:2, 78:8-23, 81:25-82:7.). Nagai also testified that [redacted]. (Ex. 8, 168:2-17, 129:11-130:12.)

Narisada did not know about the Alleged Withheld References during the prosecution of the '350 and '351 patents. (Ex. 9, 109:7-l5, 124:11-23, 167:2-168:20; Ex. 7 at 6-7.) Narisada testified that [redacted] (Ex. 9, 167:2-168:20). Narisada also testified that [redacted]

[2] To minimize the burden on the Court, Sysmex's only submits select pages from certain voluminous exhibits filed herewith. Upon request, Sysmex will submit full exhibits.

[redacted]. (*Id.*, 109:7-l5, 124:11-23.)

C. Legal Standard

1. Summary Judgment

At the summary judgment stage, the moving party has the burden of demonstrating the absence of a genuine issue of fact for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). This burden may be met by showing that there is an absence of evidence to support the nonmoving party's case. *Id.* at 325. If the moving party satisfies this burden, the opposing party must go beyond the pleadings and "set forth specific facts" to show a genuine issue for trial. *Id.* at 321 n.3, 333-34. Indeed, because BCI bears the burden of proof for invalidity and unenforceability by clear and convincing evidence, it must do "more than simply raise some doubt." *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1359 (Fed. Cir. 1998). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.*

2. Inequitable Conduct

To prevail on a claim of inequitable conduct, the accused infringer must prove by clear and convincing evidence: (1) that the patentee "acted with the specific intent to deceive the PTO" and (2) but-for materiality. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). Importantly, knowledge of the alleged withheld references must be contemporaneous with the prosecution of the asserted patents. "The fact that information was known years ago does not mean that it was recognized that the information is material to the present application." MPEP § 2001.04 (emphasis added); *see also Otsuka Pharm Co. v. Sandoz, Inc.*, No. 3:07-cv-01000, 2010 WL 11636594, at *29-30 (D.N.J. Dec. 15, 2010), *aff'd*, 678 F.3d 1280 (Fed. Cir. 2012) (knowledge of information in 1987 was not sufficient to establish knowledge during prosecution in 2005); *Barry v. Medtronic, Inc.*, 245 F. Supp. 3d 793, 821 (E.D. Tex. 2017) (knowledge of alleged materiality must exist "during prosecution."); *Union Oil Co. v. Atlantic Richfield Co.*, 34 F. Supp.

2d 1208, 1212 (C.D. Cal. 1998) (knowledge requires "a present, conscious awareness, i.e., 'the duty [to disclose] applies to contemporaneously or presently known information.'"); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 723 F. Supp.2d 1284, 1314-15 (S.D. Cal. 2010) ("the fact that information was known years ago does not mean that it was necessarily recognized as being material at the time the application was filed.").

When circumstantial evidence is relied upon to meet the clear and convincing standard, knowledge and specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence." *Therasense* at 1290. "Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Id.* at 1290-91.

D. There Is No Evidence Of Knowledge Or Deceptive Intent By Horie

1. No knowledge of the Alleged Withheld References during prosecution

BCI's counterclaim only alleges that Horie was "aware of the materiality" of the XE-2100 analyzer with Body Fluid Application and the XE-2100 IPU Manual. (D.I. 302, ¶¶ 12-13, 15.) This unsupported allegation is pure speculation, which does not qualify as clear and convincing evidence. *Easton Tech. Prods. v. Feradyne Outdoors, LLC,* No. 18-1222-RGA, 2019 WL 1513463, at *6 (D. Del. April 8, 2019) (generally alleging that individuals have knowledge of prior art is insufficient to "allow for the reasonable inference that [the individuals] had knowledge of the [allegedly withheld reference].") BCI must go beyond its counterclaim allegations to avoid summary judgment. *Celotex*, 477 U.S. at 323-24.

BCI has offered no direct evidence that Horie had knowledge of the XE-2100 with Body Fluid Application, the XE-2100 Main Unit Manual and the XE-2100 IPU Manual any time during prosecution of the applications for the '350 and '351 patents. To the contrary, Horie testified that he has no recollection of the XE-2100 analyzer with body fluid application prior to September 2019, and the first time he saw the XE-2100 Main Unit Manual and the XE-2100 IPU Manual was

after this lawsuit was filed. (Ex. 6, 109:19-110:4, 104:8-106:10, 131:19-133:24; *see also* Ex. 7 at 6-7.) In view of these undisputed material facts, and BCI's lack of evidence establishing that Horie had knowledge of the alleged withheld references during the prosecution of the Asserted Patents, summary judgment is proper. *Therma-Tru Corp. v. Peachtree Doors, Inc.*, 44 F.3d 998, 995 (Fed. Cir. 1995) ("There can not have been culpable intent in withholding information that the inventor did not have."); *Barry*, 245 F. Supp. 3d at 818, 821-23 (no inequitable conduct where there was no evidence establishing knowledge of alleged withheld references during prosecution).

2. BCI Cannot show that the single most reasonable inference is that Horie had knowledge of the Alleged Withheld References

BCI tries to infer knowledge with allegations that (i) Horie prosecuted over 400 Sysmex applications covering a twenty year period, and (ii) a portion of a different version of the XE-2100 Main Unit Manual was cited during the prosecution of one unrelated application three years before the prosecution of the Asserted Patents. (D.I. 302, ¶¶ 56-57.) BCI's argument essentially seeks an inference that Horie remembered every reference he ever looked at while prosecuting over 400 applications over a twenty year period and specifically remembered and recognized the alleged materiality of a portion of a different version of the XE-2100 Main Unit Manual that was cited in prosecution three years before the prosecution of the Asserted Patents. This is an unreasonable inference. *Otsuka*, 2010 WL 11636594, at *29-30 (knowledge of information in 1987 was not sufficient to establish knowledge during prosecution in 2005). Instead, these allegations support the reasonable inference that Horie *did not* have contemporaneous knowledge of the alleged withheld XE-2100 Main Unit Manual during the prosecution of the Asserted Patents. *Union Oil*, 34 F. Supp. 2d at 1212 ("'duty [to disclose] applies to contemporaneously or presently known information.'"); *Barry*, 245 F. Supp. 3d at 821; *Presidio*, 723 F. Supp.2d at 1314-15; MPEP § 2001.04. In fact, this is exactly the case, as Horie did not recall seeing or having knowledge of the

XE-2100 Main Unit Manual (and the XE-2100 with body fluid application and the XE-2100 IPU Manual) prior to the institution of this lawsuit.[3] (Ex. 6, 109:19-110:4, 104:8-106:10, 131:19-133:24.)

Knowledge also cannot be inferred from Horie's refusal to answer questions based on the attorney-client privilege and work product immunity as pled in ¶ 60 of BCI's counterclaim (D.I. 302). *See Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344 (Fed. Cir. 2004) (no adverse inference can be drawn from attorney-client privilege). BCI's questions improperly sought Horie's protected work product and attorney-client communications. (Ex. 6, 114:4-119:11 (e.g., asking "Do you believe that Figure 1 of the 350 patent on the left was novel over the prior art?").)

BCI cannot establish that the single most reasonable inference is that Horie knew about the Alleged Withheld References during prosecution of the Asserted Patents.

3. There is no evidence that Horie had an intent to deceive

BCI offers no direct evidence of deceptive intent, and there is insufficient evidence to establish that the single most reasonable inference is that Horie intended to deceive the PTO. As explained above, an equally reasonable, if not more reasonable, inference is that Horie did not have knowledge of the Alleged Withheld References during the prosecution of the Asserted Patents. Without knowledge, there cannot be deceptive intent. *Therma-Tru*, 44 F.3d at 995.

[3] BCI has no support for its allegation that Horie was aware of the XE-2100 Main Unit Manual that was cited in an unrelated Sysmex 2006 published patent application that he did not prosecute. (D.I. 302, ¶ 58.) Even if Horie had knowledge of the existence of the 2006 published application, it is undisputed that the application published thirteen years before the prosecution of the Asserted Patents and that Horie was not involved in the prosecution. The single most reasonable inference is that Horie had no knowledge about the 2006 publication and the references cited in that unrelated patent application. *Otsuka*, 2010 WL 11636594, at *29-30; *St. Clair Intellectual Property Consultants Inc. v. Acer Inc.*, 961 F. Supp. 2d 610, 618-19 (D. Del. 2013) (no knowledge inferred when attorney did not prosecute application where reference was first disclosed).

Moreover, Horie's undisputed submission to the PTO of the information that BCI relied upon in the European proceedings refutes a single most reasonable inference that Horie withheld information with an intent to deceive; instead, it is objective evidence of candor and good faith that supports an inference that there was no deceptive intent. *Exergen Corp. v. Wal-Mart Stores, Inc*., 575 F.3d 1312, 1329 n.5 (Fed. Cir. 2009) (a reasonable inference can be drawn from objective indications of candor and good faith.); *Mycone DentalSupply Co. v. Creative Nail Design, Inc.*, No. 11-4380 (JBS-KMW), 2013 WL 3216145, at *7 (D.N.J June 24, 2013) (disclosure of other prior art is "objective indication of candor that impedes any reasonable inference that [plaintiff] intended to deceive the PTO."); *Pac Biosciences, Inc. v. Oxford Nanopore Techs.*, No. 17-1353-LPS, 2019 WL668843, at *3 (D. Del. Feb. 19, 2019) (disclosure of a patent during prosecution militates against inference of bad faith).

BCI's allegations relating to Horie's involvement in prosecuting an unrelated patent where a different version of the XE-2100 Main Unit Manual was cited is immaterial, as it insufficient to infer intent. *Exergen*, 575 F.3d at 1331 ("the mere fact that an applicant disclosed a reference during prosecution of one application, but did not disclose it during prosecution of a related application, is insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct."); *St. Jude Med, Cardiology Div., Inc. v. Volcano Corp.*, No. 12-441-RGA, 2014 WL 2622240, at *2 (D. Del. June 11, 2014) (failure to disclose a prior art reference that the same attorney had cited during the prosecution of a different patent is insufficient to infer intent).

BCI sums up its "specific intent" proof for Horie (and Nagai and Narisada) based on six purported allegations, none of which are sufficient to infer deceptive intent. (D.I. 302, ¶ 69.) ***First***, BCI's allegation that the Alleged Withheld References are material and were not disclosed is

irrelevant as a matter of law. *Exergen,* 575 F.3d at 1331 (deceptive intent cannot be inferred from allegation that "information having some degree of materiality was not disclosed."); *Optium Corp. v. Emcore Corp*., 603 F.3d 1313, 1321 (Fed. Cir. 2010) (affirming summary judgment of no inequitable conduct, stating "Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent."); *Easton*, 2019 WL 1513463, at *7 ("intent cannot be solely inferred from materiality"); *Invista N. Am. S.A.R.L. v. M&G USA Corp.*, No. 11-1007-SLR-CJB, 2013 WL 12304544, at *11 (D. Del. May 3, 2013) (same). ***Second***, even assuming Horie (or Nagai and Narisada) was aware of the Allegedly Withheld References, mere knowledge is insufficient to infer deceptive intent. *Exergen,* 575 F.3d at 1331 (knowledge based on prior prosecution "is insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct."); *St. Jude*, 2014 WL 2622240, at *2 (knowledge of previously cited prior art is insufficient to infer intent). ***Third***, deceptive intent cannot be inferred based on Horie's (or Nagai's and Narisada's) involvement with prosecution activities. *Exergen,* 575 F.3d at 1331; *St. Jude*, 2014 WL 2622240, at *2. ***Fourth***, deceptive intent cannot be inferred from the allegation that Horie (or Nagai and Narisada) could have provided the information to the PTO. *Senju Pharm. Co. v. Apotex, Inc.*, 717 F. Supp. 2d 404, 430 (D. Del. 2010) ("Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding a deceptive intent."). ***Fifth***, intent to deceive cannot be inferred from the allegation that "Sysmex's interest in obtaining patents that could form a basis for a countersuit." *Invista,* 2013 WL 12304544, at *11 (deceptive intent not reasonably inferred from allegation that applicant had a "motive to deceive the PTO" because of a "desire to acquire patent rights in the gas barrier market"). ***Sixth***, BCI's allegation that Horie (or Nagai and Narisada) were silent when the Asserted Patents issued cannot support a reasonable inference of

intent to deceive. *Senju,* 717 F. Supp. 2d at 430. BCI's argument (D.I. 302, ¶ 69) that these six irrelevant allegations "taken together" are somehow sufficient does not add up; six times zero relevance is still zero relevance.

E. There Is No Evidence Of Knowledge Or Deceptive Intent By Nagai

1. No knowledge of the Alleged Withheld References during prosecution

BCI's counterclaim only alleges that Nagai was "aware of the materiality" of the XE-2100 Main Unit Manual. (D.I. 302, ¶¶ 12-13, 15.) This unsupported allegation is speculation and is not clear and convincing evidence of anything. *Easton*, 2019 WL 1513463, at *6.

BCI has offered no direct evidence that Nagai had knowledge of the Alleged Withheld References during the prosecution of the Asserted Patents. To the contrary, Nagai testified that [redacted]. (Ex. 8, at 39:20-40:4, 41:4-11, 42:7-43:2, 78:8-23, 81:25-82:7.) Nagai testified that [redacted]. (Ex. 8, 168:2-17, 129:11-130:12; *see also* Ex. 7 at 6-7). In view of these undisputed material facts, and BCI's lack of evidence establishing that Nagai had knowledge of the Alleged Withheld References during the prosecution of the Asserted Patents, summary judgment is proper. *Therma-Tru*, 44 F.3d at 995; *Barry* at 818, 821-23.

2. BCI cannot show that the single most reasonable inference is that Nagai had knowledge of the Alleged Withheld References

BCI tries to infer knowledge by alleging that [redacted] (D.I. 302, ¶¶ 52-53.) However, this allegation is insufficient to establish that the single most reasonable inference is that Nagai was aware of the Alleged Withheld References 15 years later during the prosecution of the Asserted Patents in 2018-2019, especially in view of

Nagai's testimony that [redacted]. *Otsuka*, 2010 WL 11636594, at *29-30; *Union Oil*, 34 F. Supp. 2d at 1212*; Presidio*, 723 F. Supp.2d at 1314-15. Further, Nagai was [redacted]. (Ex. 8, 179:21-183:2) [redacted]. (*Id.* at 85:15-86:5.) These facts support the equally reasonable, if not more reasonable, inference that Nagai had no knowledge of any of the Alleged Withheld References in 2004 or nearly 15 years later during the prosecution of the Asserted Patents.[4] *Aero Transportation Prods., Inc. v. Miner Enter., Inc.*, No. 06-00837-JTM, WL 10672590, at *4-5 (W.D. Mo. Aug. 3, 2009) (no knowledge where inventor was a "CC" recipient on memo disclosing withheld information and inventor had no recollection of seeing the memo).

Finally, knowledge cannot be inferred from BCI's counterclaim ¶ 55 assertion (D.I. 302) that Nagai "[redacted]." *St. Clair*, 961 F. Supp. 2d at 618-19. Thus, BCI has no clear and convincing evidence that the single most reasonable inference is that Nagai had knowledge of the Alleged Withheld References during prosecution of the Asserted Patents.

3. There Is No Evidence That Nagai Had An Intent To Deceive

BCI offers no direct evidence of deceptive intent, and BCI has no evidence from which intent to deceive is the single most reasonable inference. Based on Nagai's deposition and

[4] BCI does not plead any facts to support its allegation "on information and belief" as to what allegedly occurred in March 2004. If such facts had existed, BCI was required to include them in its counterclaim. *Exergen,* 575 F.3d at 1330 (Pleadings "on information and belief" are permitted under Rule 9(b) only if the pleading sets forth the specific facts upon which the belief is reasonably based.)

Sysmex's interrogatory response, there is a reasonable inference that during prosecution Nagai [redacted]. *Precision Fabrics Grp., Inc. v. TieTex Int'l, Ltd.*, 2016 U.S. Dist. LEXIS 161336, at *37-39 (M.D.N.C. Nov. 21, 2016) (granting summary judgment of no inequitable conduct because intent to deceive cannot be inferred where inventor "testified that he had no recollection of ever having seen the references" and challenger "fail[ed] to point to any portion of [deponent's] testimony to suggest that he intentionally withheld these references.").

Thus, in contrast to inferring an intent to withhold, an equally reasonable, if not more reasonable, inference is that during prosecution Nagai [redacted]. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) ("Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference."); *Intercontinental Great Brands LLC v. Kellogg North Am. Co.*, 118 F. Supp. 3d 1022, 1045 (N.D. Ill. 2015) (No intent to deceive because "alternative reasonable inference can be drawn" including that "[inventor] did not see the e-mail [or] that he forgot about the email"). Without knowledge, there cannot be deceptive intent. *Therma-Tru*, 44 F.3d at 995.

Finally, as explained in Section IV.D.3, BCI alleges "specific intent" based on six purported allegations, each of which are irrelevant and insufficient to infer deceptive intent. (D.I. 302, ¶ 69.) These arguments and explanations apply equally to Nagai.

F. There Is No Evidence Of Knowledge Or Deceptive Intent By Narisada

1. No knowledge of the Alleged Withheld References during prosecution

BCI's counterclaim only alleges that Narisada was "aware of the materiality" of the XE-2100 Main Unit Manual. (D.I. 302, ¶¶ 12-13, 15.) This unsupported allegation is pure speculation;

it is not clear and convincing evidence. *Easton*, 2019 WL 1513463, at *6.

BCI has offered no direct evidence that Narisada had knowledge of the Allegedly Withheld References during prosecution of the Asserted Patents. To the contrary, Narisada testified that [redacted] (Ex. 9, 167:2-168:20). [redacted]. (*Id.*, 109:7-15, 124:11-23; *see also,* Ex. 7 at 6-7.) In view of these undisputed material facts, and BCI's lack of evidence establishing that Narisada had knowledge of the Alleged Withheld References during the prosecution of the Asserted Patents, summary judgment is proper. *Therma-Tru*, 44 F.3d at 995; *Barry*, 245 F. Supp. 3d at 818, 821.

2. BCI Cannot show that the single most reasonable inference is that Narisada had knowledge of the Alleged Withheld References

BCI tries to infer knowledge based on allegations that Narisada [redacted]. (D.I. 302, ¶ 54). However, this allegation as to what may have occurred in 2004 is insufficient to establish that the single most reasonable inference is that Narisada was aware of the Alleged Withheld References 15 years later during the prosecution of the Asserted Patents, especially in view of Narisada's testimony that [redacted]. *Otsuka*, 2010 WL 11636594, at *29-30; *Union Oil*, 34 F. Supp. 2d at 1212; *Presidio*, 723 F. Supp.2d at 1314-15. Further, BCI fails to point to any express statements [redacted]. Moreover, Narisada testified that [redacted]. (Ex. 9, 137: 4-11; 141:4-22; 145:11-16). This testimony alone demonstrates that the single most reasonable inference *cannot* be that Narisada knew of the document in 2004-05. Furthermore, even if one could infer

Narisada knew of the Alleged Withheld References in 2004-05, BCI fails to provide any facts demonstrating that the single most reasonable inference is that he recalled the 2004 email or the Alleged Withheld References 15 years later during prosecution of the Asserted Patents. *Otsuka*, 2010 WL 11636594, at *29-30; *Union Oil*, 34 F. Supp. 2d at 1212; *Barry*, 245 F. Supp. 3d at 821; *Presidio*, 723 F. Supp.2d at 1314-15; MPEP § 2001.04.

BCI's ¶ 55 counterclaim allegation (D.I. 302) about [redacted] is immaterial as to whether he knew of the Alleged Withheld References and cannot establish that the single most reasonable inference is that he knew of them during prosecution of the Asserted Patents. *St. Clair*, 961 F. Supp. 2d at 618-19. Finally, BCI's ¶ 55 allegation that Narisada prepared a report relating to the LH 700 operation for use in the European litigation establishes nothing with respect to his knowledge about the Alleged Withheld References. *Exergen*, 575 F.3d at 1331; *St. Jude*, 2014 WL 2622240, at *2. Moreover, the LH 700 report was provided to the examiner during the prosecution of the Asserted Patents. (Exs. 1-2 (under References Cited: "D35 Technical testing of Beckman Coulter LH 750, dated Oct. 18, 2018").) Thus, BCI has no clear and convincing evidence that the single most reasonable inference is that Narisada had knowledge of the Alleged Withheld References during prosecution of the Asserted Patents.

3. There Is No Evidence Of Intent To Deceive The PTO By Narisada

BCI offers no direct evidence of deceptive intent, and BCI has no evidence to establish that the single most reasonable inference is that Narisada intended to deceive the PTO. Based on the evidence (Ex. 9, 109:7-l5, 124:11-23; *see also,* Ex. 7 at 6-7), there is a reasonable inference that during prosecution, Narisada did not recall documents from 14-15 years earlier. *Precision Fabrics*, 2016 U.S. Dist. LEXIS 161336, at *37-39. Thus, in contrast to inferring an intent to deceive, an equally reasonable, if not more reasonable, inference is that during prosecution

Narisada simply did not recall documents from 14 years ago. *Scanner Techs*, 528 F.3d at 1376; *Intercontinental Great Brands*, 118 F. Supp. 3d at 1045. Without knowledge, there cannot be deceptive intent. *Therma-Tru*, 44 F.3d at 995.

Finally, as explained in Sections IV.D.3, BCI alleged "specific intent" based on six purported allegations, each of which is immaterial and insufficient to infer deceptive intent. (D.I. 302, ¶ 69.) The reasoning above applies equally to Narisada.

V. DISMISSAL OF INVALIDITY BASED ON ADVIA2120 PRODUCT

A. Summary of the Argument

BCI alleges that some of the Asserted Claims of the '350 and '351 patents are invalid under the on-sale bar of 35 U.S.C. § 102(b) based on two different products, the Advia2120 and Advia 120. (Ex. 10 at 39-41.) However, BCI has no evidence establishing that the Advia2120 was on-sale in the U.S. prior to the critical date. Further, BCI has no evidence showing how the Advia2120 and Advia 120 operate. BCI's Rule 30(b)(6) witness testified that the *only* Advia product that he could identify prior to critical date was the Advia 120, but he could not provide any details about the design and operation of the product.

B. Undisputed Facts Regarding Advia2120

The critical date for the Asserted Patents is January 31, 2007. (Ex. 11, ¶23; Exs. 1-2.)

Prior to Advia2120 being identified as a ground for invalidity based on the on-sale bar, BCI identified "the Advia series" of products as being acceptable, non-infringing alternatives. (Ex. 12 at 2-3.) Sysmex served a Rule 30(b)(6) deposition notice directed to BCI's alleged "non-infringing alternatives" and invalidity grounds. (Ex. 13, Topics 7 and 14-17.) BCI's long-time employee, Eric Grace, was designated as BCI's corporate witness for these topics. (Ex. 4, 10:11-25.) He testified that as part of his Rule 30(b)(6) investigation, the *only* Advia product he identified in the marketplace prior to the critical date that was used to analyze body fluids was the

Advia 120. (*Id.* at 187:4-188:2.) However, Grace could not provide any details about the operation of the Advia 120 or any other Advia analyzer. (*Id.* at 10:11-25, 12:10-13:16, 14:22-17:14, 19:13-20:21.) Grace made clear that his knowledge of the commercial status of the Advia 120 was really only a "belief" based on "a clearance for body fluid application" for the Advia 120 that he thought occurred in 2000. (*Id.* at 187:4-188:2.) Grace provided no testimony about the Advia2120.

The other witnesses identified in BCI's Rule 26(a) Disclosures also had no information about Advia2120 or Advia 120. Grace was the *only* person identified in BCI's Rule 26(a) Disclosures as having knowledge relating to "prior art products and publications." (Ex. 14 at 2; Ex. 15 at 4.) During his personal deposition, Grace specifically testified that he was aware of the existence of the Advia series of products "but not of the design or operation of the Advia series." (Ex. 16, 17:20-18:7.) BCI's longtime employee, Dunbabin, also had no knowledge about the Advia products. (Ex. 17, 201:20-202:3; Ex. 14 at 3.) BCI's Director of Sales, who was identified as having information about BCI's business operations and sales information, also had no information about the Advia products and only recalled that they measured blood. (Ex. 18, 71:21-73:14, 78:9-13; Ex. 14 at 3.) BCI's Vice President and General Manager, who was identified as having knowledge about BCI's business operations, did not know when any Advia product was released. (Ex. 19, 68:2-10; Ex. 14 at 2.) BCI's Vice President of Sales was not able to provide an identification of any particular Advia series product that competed in the market and had no personal knowledge of how Advia products operated. (Ex. 20, 24:18-25:18, 29:2-6; Ex. 14 at 3.)

BCI's invalidity expert, Mr. Roche, provided an Opening Report (Ex. 11) and a Reply Report (Ex. 21) that included an opinion that certain claims were invalid based on the Advia2120. (Ex. 11, ¶¶ 195-203, 220-226 and App. G-H; Ex. 21, ¶¶ 77-85.) Roche provided no invalidity

opinions based on the Advia 120, only Advia2120. (*Id.*) Neither of Roche's invalidity reports provide any facts establishing that the Advia2120 was on-sale in the U.S. prior to the critical date.

Roche relies on three documents for his understanding of how Advia2120 allegedly operated. (Ex. 11, ¶ 196.) First, Roche relies on an operator manual that has a 2007 copyright date and a print date of March 2008 (more than one year *after* the critical date). (*Id.*; Ex. 22 ("Advia-OG").) The Advia-OG specifically states that the information in the operator's guide was "correct at the time of printing." (Ex. 22 at BCID233033.) Second, Roche relies on a U.S. Food and Drug Administration 510(k) application for the Advia 120, which makes no mention of the Advia2120. (Ex. 23 ("K003796"); Ex. 11, ¶ 196.) Third, Roche relies on Patent Application Publication No. 2003/0215890 ("Ornstein"), which also makes no mention of the Advia2120. (Ex. 24; Ex. 11, ¶ 196.)

C. Legal Standard

The on-sale bar under 35 U.S.C. § 102(b) applies when, before the critical date, the claimed invention (1) was the subject of a commercial offer for sale in the United States; and (2) was ready for patenting. *Pfaff v. Wells Elecs*, 525 U.S. 55, 67-68 (1998). For the first prong of the *Pfaff* analysis, the "transaction at issue must be a 'sale' in a commercial law sense" and courts will look to the Uniform Commercial Code ("UCC") to determine if a communication or contract "rises to the level of a commercial offer for sale" or a commercial "sale." *Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363, 1373 (Fed. Cir. 2016). BCI bears the "burden of proving that there was a definite sale or offer to sell more than one year before the application for the subject patent, and that the subject matter of the sale or offer to sell fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art." *See UMC Elecs. Co. v. United States*, 816 F.2d 647, 656-57 (Fed. Cir. 1987). BCI must provide clear and convincing evidence to meet its burden. *Abbott Labs. v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1318 (Fed. Cir. 1999).

In the absence of such evidence, summary judgment of no invalidity is appropriate. *Celotex*, 477 U.S. at 323-24.

D. BCI Has No Evidence That Advia2120 Was On Sale Prior to the Critical Date

BCI has no evidence establishing that the Advia2120 was on-sale in the U.S. prior to the January 31, 2007 critical date.[5] BCI's Rule 30(b)(6) witness, Grace, testified that he believed that the only product in the marketplace prior to February 2007 that was used to analyze body fluids was the Advia 120. (Ex. DAP17 at 187:4-188:2.) Grace and the other BCI witnesses provided no testimony whatsoever about the Advia2120.

Roche likewise provided no evidence establishing that the Advia2120 was on-sale in the U.S. prior to the critical date. Instead, Roche makes only the unsupported statement that:

> The Advia 120 was later improved and marketed as the Advia 2120. ("Advia2120"). Around 2006, I was generally aware of the state-of-the-art in hematology analyzer systems, which included the Advia2120.

(Ex. 11, ¶ 195.) Roche's conclusory, uncorroborated statements do not provide clear and convincing evidence of a single sale or offer for sale of the Advia2120 in the U.S. prior to the critical date. *See Lacks Indus. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1349 (Fed. Cir. 2003) (affirming summary judgment of no on-sale bar because no corroboration concerning a sale prior to the critical date); *Lucent Techs. v. Microsoft Corp.*, 544 F. Supp. 2d 1080, 1091-92 (S.D. Cal. 2008) (granting summary judgment of no anticipation in view of "conclusory" invalidity expert report, noting "It is not the task of the district court to attempt to interpret confusing or general testimony to determine whether a case of invalidity has been made out, particularly at the summary judgment stage." (citing *Schumer v. Lab. Comput. Sys.*, 308 F.3d

[5] BCI has not alleged "in public use" or any other invalidity basis under 35 U.S.C. § 102(b), nor has BCI provided any evidence to support any other basis.

1304, 1316 (Fed. Cir. 2002))). Thus, there is no genuine issue of material fact that BCI failed to provide sufficient evidence to support BCI's "on-sale" invalidity theory based on Advia2120.

E. BCI Has No Evidence Regarding the Design and Operation of the Advia2120

BCI's lack of clear and convincing evidence that the Advia2120 was sold in the U.S. prior to the critical date is a sufficient basis to grant summary judgment. A second, independent basis is that BCI has no evidence showing the design and operation of the Advia2120. None of BCI's witnesses could provide any information about the design and operation of any Advia series products. (Ex. 4 at 14:22-17:14, 19:13-20:21; Ex. 16 at 17:20-18:7; Ex. 17 at 201:20-202:3; Ex. 18 at 71:21-73:14, 78:9-13; Ex. 19 at 68:2-10; Ex. 20 at 24:18-25:18, 29:2-6.)

Roche relies on three unrelated documents – Advia-OG, K003796, and Ornstein – as support for his invalidity opinion based on the Advia2120. (Ex. 11, ¶ 196.) Indeed, Roche's claim charts for the Advia2120 cite only these three documents. (Ex. 11 at App. G-H.) However, none of these documents relate to or describe an Advia2120 that existed prior to the critical date.

1. Advia-OG describes only products that existed after the critical date

There is no evidence that the Advia-OG existed prior to March 2008. The cover page specifically is dated "2008-03" meaning the Advia-OG document was printed in March 2008. (Ex. 22 at BCID233031; Ex. 25, ¶¶ 1051, 1054.) In addition, the third page of Advia-OG states: "The information in this operator's guide was *correct at the time of printing*." (Ex. 22 at BCID233033 (emphasis added).) In other words, Advia-OG expressly describes itself as only being "correct at the time of printing," which was on or after March 2008. (*Id.*; Ex. 25, ¶ 1052.) There is no evidence that the Advia-OG correctly describes anything, let alone an Advia2120, prior to the January 31, 2007 critical date. (Ex. 25, ¶¶ 1051-52, 1054; Ex. 22 at BCID233031-33.)

Roche's conclusory statement that Advia-OG "was available by 2007" is unsupported. (Ex. 11, ¶ 196.) Roche provides no factual basis for that statement and in his Reply report he did

not dispute that March 2008 was the print date for Advia-OG. (Ex. 21, ¶¶77-85, 110-13.)[6] The 2007 copyright date in Advia-OG does not provide clear and convincing evidence that it describes a product that existed prior to the January 31, 2007 critical date. (Ex. 22 at BCID233033; Ex. 25, ¶ 1053.) The 2007 copyright fails to distinguish between the first month of 2007, which is before the critical date, and the next eleven months of 2007, which fall *after* the critical date. BCI's attempted reliance on a 2007 copyright date is not clear and convincing evidence required for patent invalidity. *See Lectrolarm Custom Servs. v. Vincon Indus.*, No. 03-2330 Ma/A, 2006 U.S. Dist. LEXIS 7482, at *9 (W.D. Tenn. Feb. 6, 2006) ("[c]apabilities described in the [1988] Owners Manual cannot be considered by the court in its analysis of claim invalidity because, given only a copyright year of 1988, the court has insufficient information to determine whether the Owners Manual was published before or after [the critical date] May 12, 1988."); *CNET Networks, Inc. v. Etilize, Inc.*, 584 F. Supp. 2d 1260, 1273-74 (N.D. Cal. 2008) ("the court finds that a 2001 copyright date does not prove the [prior art user guide] was publicly accessible prior to [the April 2001 critical date]"); *Navico Inc. v. Garmin Int'l, Inc.*, No. 2:16-CV-00190-JRG-RSP, 2017 WL 3750252, at *3 (E.D. Tex. July 28, 2017) (rejecting argument that copyright date is evidence of printed publication).

Further, it is BCI's burden to show that the Advia-OG from March 2008 accurately describes the operations of an Advia2120 on sale in the U.S. on or before January 31, 2007, and

[6] Roche's unsupported statement that Advia-OG "was submitted to the Taiwan Food and Drug Administration" also proves nothing. (Ex. 11, ¶ 196.) Roche provides no evidence as to when this alleged Taiwan FDA submission occurred, who made the submission, whether the submission was public or private, why it was submitted, how it was submitted, or when it was available to the public. Further, the alleged submission would have occurred after March 2008, because an English translation of the corresponding Mandarin version cover page of Advia-OG states "Revision B, March of 2008" – further confirming Advia-OG was printed in March 2008 or later. (Ex. 22 at BCID233510.)

simply having the same name or "designation" (Advia 2120) "isn't enough of a connection to infer" it is "applicable" to the earlier system at summary judgment. *See Navico,* 2017 WL 3750252, at *4 ("Here, the only document *potentially* describing the 2002 system is the 2007 Operator Manual, but the only connection between the two is use of [the same product name] designation. The court finds that isn't enough of a connection to infer the 2007 Manual is applicable to the 2002 system."). Like *Lectrolarm* and *Navico*, BCI has not presented clear and convincing evidence that Advia-OG describes any product that was on-sale in the U.S. prior to the January 31, 2007 critical date.

2. K003796 does not describe the Advia2120.

Roche states that K003796 is a "U.S. Food & Drug Administration 510(k)(003796) that was available by 2003." (Ex. 11, ¶ 196; Ex. 23.) Roche provides no basis for his statement and does not even identify where or how he obtained K003796. Nonetheless, K003796 makes no reference to Advia2120 whatsoever. (Ex. 23.) K003796 is directed to the Advia 120, but BCI has not presented any evidence of how the Advia 120 relates the Advia2120 other than it being a "predecessor" product (Ex. 11, ¶ 201). BCI also has not presented any evidence as to whether K003796 for the Advia 120 provides an accurate description of how a different product – the Advia2120 – operated on or before January 31, 2007. Roche's own statements confirm that Advia 120 in K003796 is different from Advia2120: "Advia 120 was later improved and marketed as the Advia 2120." (*Id.*, ¶ 195.) Roche provides no evidence supporting this conclusory statement, nor does he identify and explain the differences between Advia 120 and Advia2120 and whether they relate to limitations of the Asserted Claims. (*Id.*, ¶¶ 195-203.)

By comparison, Sysmex's validity expert, Dr. Robinson, identified numerous differences between the operator procedures described in the K003796 (Advia 120 product) and Advia-OG (Advia2120 product), and Roche failed to specifically address these differences on reply. (Ex. 25,

¶¶1057, 1071-73 & n.523; Ex. 21, ¶¶77-85.) These undisputed differences establish that Advia2120 and Advia 120 are different products that operate differently. *United States v. Donovan*, 661 F.3d 174, 185-88 (3d Cir. 2011) (summary judgment is proper where expert testimony or reports satisfy the movant's burden and are not contradicted by the nonmovant). BCI has not presented clear and convincing evidence that K003796 describes an Advia2120 that was on-sale in the U.S. prior to the critical date.

3. Ornstein does not describe the Advia2120.

Ornstein (Ex. 24) makes no reference to Advia2120. Instead, it refers only to Advia 120.[7] Roche expressly admits that "Ornstein describes the operation of the Advia 120 analyzer," not the Advia2120. (Ex. 11, ¶ 201.) Despite a complete absence of any description of Advia2120, Roche states that the "design and operation of the Advia2120 is described in" Ornstein, but provides no basis for his statement. (Ex. 11, ¶ 197.) Again, Dr. Robinson pointed out the deficiencies in Roche's statement about Ornstein (Ex. 25, ¶ 1058), and Roche's reply failed to dispute or otherwise address the deficiencies. (Ex. 21, ¶¶ 77-85.) BCI has not presented clear and convincing evidence that Ornstein describes an Advia2120 product on-sale in the U.S. prior to the January 31, 2007 critical date.

4. Roche's personal experience is not clear and convincing evidence

Recognizing that BCI has no evidence linking Advia-OG, K003796 or Ornstein to an Advia2120 that was on-sale in the U.S. prior to the critical date, BCI and Roche attempt to rely on Roche's "personal experience including conversations with former Bayer employees." (Ex. 21, ¶ 77 (citing to Ex. 11, ¶¶ 195-96, 226).) However, Roche's reports are silent as to *what* specific facts he learned during his personal experience in the field, *when* he learned such facts (*e.g.,* prior

[7] Sysmex does not concede that Ornstein accurately describes any Advia product that was on-sale in the U.S. prior to the critical date, but that issue is outside the scope of this motion.

to the critical date or as a retained expert), and *how* any such facts are corroborated by evidence of record. In fact, Roche's reports do not disclose any personal experience relating to Advia2120 as part of his qualifications or at any time in his career. (Ex. 11, ¶¶ 1-17, 61-77; Ex. 11 at App. A.) Roche's vague, uncorroborated "personal experience" is not clear and convincing evidence sufficient to establish patent invalidity. *Lacks*, 322 F.3d at 1350 ("courts have consistently required documentary corroboration of oral testimony by interested parties presented to invalidate a patent"); *Lucent Techs.*, 544 F. Supp. 2d at 1091-92.

BCI's and Roche's citation to "discussions with David Zelmanovic and Pam Elsins, both co-inventors of the Ornstein patent, as well as John Cremins, a purported product developer for the Advia 120/2120" also is insufficient to avoid summary judgment. (Ex. 11, ¶ 226; Ex. 21, ¶ 77.) Roche's reports are silent as to *what* specific facts he learned from these discussions, *who* provided the facts, *how* any such facts are corroborated by evidence of record, *when* the discussions occurred, *where* the discussions occurred, and the *circumstances* for the discussions. Roche also fails to connect any of the unspecified facts he learned from his "discussions" to any evidence of record that supports BCI's invalidity theory. Further, Roche's undocumented discussions with third-parties is classic impermissible hearsay that cannot be relied upon to meet its burden to provide clear and convincing evidence of facts to prove patent invalidity. *Wi-Lan Inc. v. Sharp Elec. Corp.,* 992 F.3d 1366, 1375 (Fed. Cir. 2021) (expert cannot be used as conduit for hearsay; "the appropriate way to adduce factual details of specific past events is, where possible, through persons who witnessed those events." (citing *Marvel Characters, Inc. v. Kirby*, 726 F.3d 119, 136 (2d Cir. 2013))); *Arnold Pontiac-GMC, Inc. v. Budd Baer, Inc.*, 826 F.2d 1335, 1339 n.3 (3d Cir. 1987) ("Summary judgment, of course, looks only to admissible evidence.").

To summarize, summary judgment is warranted in view of BCI's failure to introduce any

evidence that the Advia2120 was offered for sale or sold in the U.S. prior to the January 31, 2007 critical date or of its design and operation prior to the critical date. *Celotex*, 477 U.S. at 323-24.

F. BCI Has No Evidence Regarding the Advia 120

BCI has no evidence to support a new invalidity theory based on the Advia 120. None of BCI's witnesses had any information relating to the design and operation of the Advia 120. (Ex. 4 at 14:22-17:14, 19:13-20:21; Ex. 16 at 17:20-18:7; Ex. 17 at 201:20-202:3; Ex. 18 at 71:21-73:14, 78:9-13; Ex. 19 at 68:2-10; Ex. 20 at 24:18-25:18, 29:2-6.) Further, BCI's expert, Roche, did not provide any invalidity opinion specific to the Advia 120 product, only the Advia2120. (Exs. 11; Ex. 21.) Summary judgment is warranted because BCI failed to introduce any admissible evidence of the Advia 120 design and operation. *Celotex*, 477 U.S. at 323-24.

G. BCI's Obviousness Defense Based On Advia Products Should Be Dismissed

BCI asserts that the Asserted Claims are "obvious in view of the XE-2100 + Advia 120 + General Knowledge (including Common Sense) of a PHOSITA."[8] (D.I. 382 at 3.) However, as explained in Sections V.D-F above, BCI has no clear and convincing evidence that the Advia2120 was on-sale in the U.S. prior to the critical date, no clear and convincing evidence regarding the design and operation of the Advia2120, and no clear and convincing evidence regarding the design and operation of the Advia 120. Thus, summary judgment of this obviousness ground should be granted for the same reasons.

A second independent ground for dismissing this obviousness ground is that BCI's expert has not provided any opinions based on this obviousness ground. Roche confirmed that

[8] BCI refers to the "Advia 120" as collectively being the Advia 120 and the Advia 2120. (D.I. 382 at 2). It is unclear if this invalidity ground is based on a combination of the Advia 120 and Advia 2120 or each of them separately forms an invalidity ground based on obviousness. If the latter, then BCI is asserting 90 invalidity grounds instead of the 70 allowed under the Court's order. (D.I. 40.) Regardless, summary judgment is proper under either situation.

Section VIII.C of his invalidity report sets forth his opinion regarding obviousness. (Ex. 36, 228:6-10.) However, Section VIII.C of Roche's invalidity report does not include an opinion for obviousness "in view of the XE-2100 + Advia 120 + General Knowledge (including Common Sense) of a PHOSITA." (Ex. 11, Table of Contents at Sections VIII.C.1-6.) Further, none of Roche's invalidity claim charts address this obviousness combination. (*Id.*, App. G-H.) Roche's failure to provide any opinion on this ground further warrants summary judgment. *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1267 (Fed. Cir. 2008) (holding that expert testimony was required to establish invalidity on grounds of anticipation and obviousness where the subject matter is sufficiently complex to fall beyond the grasp of an ordinary layperson)

VI. DISMISSAL OF INVALIDITY BASED ON DERIVATION

A. Summary of the Argument

BCI raised a new §102(f) derivation defense on October 29, 2021 -- five months after serving its Final Invalidity Contentions in May 2021. This defense hinges on three documents that are inadmissible hearsay, and that were not reviewed by any of the named inventors. These documents do not provide clear and convincing evidence of derivation.

B. Undisputed Facts Regarding Derivation

1. The Goffin Meyvis letter

BCI's derivation defense relies heavily on a September 2005 letter from a third-party company, Goffin Meyvis, a distributor of Sysmex products in The Netherlands. (Ex. 26; Ex. 27, ¶¶ 10-25 and 44-51.) BCI has no evidence to authenticate this letter. The author is unknown. (Ex. 28 at 38:9-13.) None of the three persons whose names appear at the end of the document were deposed. There is no evidence whether they wrote any portion of the document, or whether they merely repeated information that they had received from others.

Roche relies on [redacted]. (Ex. 27, ¶¶ 12-20.) BCI has offered no evidence of the [redacted]. (Ex. 28, 38:17-39:4.) Sysmex's expert and Roche looked for it, and could not find it. (Ex. 29, ¶ 33 (citing Ex. 27, ¶ 12); Ex. 28, 39:10-25.) There is no evidence that the Goffin Meyvis letter [redacted]. Indeed, Roche testified that he did not know where the information in the Goffin Meyvis letter came from, or the methodology used to create the data. (Ex. 28, 45:12-18, 53:3-6, 79:8-14, 80:6-20, 106:19-109:11). Further, the text immediately above the table states, [redacted], according to both parties' experts. (Ex. 26 at SCorp-Del00270308 (emphasis added); Ex. 29, ¶ 38; Ex. 28, 112:3-23.)

The first page of DDX 173 is an email, which purportedly attaches the Goffin Meyvis letter, and includes Imazu in the "To:" field. (Ex. 26 at SCorp-Del00270307.) BCI advised the Court that "Mr. Imazu is the only named inventor to have received [the Goffin Meyvis] letter." (D.I. 351, p. 1.) At his deposition, Imazu [redacted]. (Ex. 30, 52:11-15; 56:7-57:4.) BCI has no evidence that Imazu ever reviewed the document. (Ex. 28, 58:14-21.)

2. The SEG proposal

BCI's derivation defense also relies heavily on a document that BCI characterizes as the SEG proposal. (Ex. 31; Ex. 27, ¶ 26.) The proposal itself is 80 pages long. (Ex. 31 at SCorp-Del00276642-721.) It was purportedly attached to an email forwarded to Imazu on January 6, 2006. (*Id.* at SCorp-Del00276639.) Roche alleges that [redacted]. (Ex. 32, ¶ 23; Ex. 8, 126:16-19; Ex. 33, 93:3-6.) However, Roche admitted that he had no evidence to support his speculation.

(Ex. 28, 142:13-144:6.) The SEG proposal also includes material taken from unidentified sources. (*e.g.*, Ex. 31 at SCorp-Del00276708-09; Ex. 28, 147:12-149:16; 150:7-17.) BCI has no testimony from anyone claiming to have authored any portion of the SEG proposal.

Roche contends that "[redacted]." (Ex. 27, ¶ 26.) Imazu only testified that [redacted] (Ex. 30, 125:17-25, 127:24-128:8, 129:9-130:6.) Further, Roche relies on only a few pages of the SEG proposal. (Ex. 31 at SCorp-Del00276645, -707, -708, -709, -712, and -713; Ex. 27, ¶¶ 26-30, 32, 35-36, 39, 53-54, 60.) BCI has no evidence that Imazu reviewed these or any other pages.[9] (Ex. 28, 139:16-140:13.) Indeed, Imazu testified that [redacted]. (Ex. 30, 129:9-131:9). Imazu's testimony is confirmed by [redacted] (Ex. 34 at SCorp-Del00334161.) By comparison, Imazu was able to provide significant testimony about documents that he had authored and seen from that time frame. (Ex. 30, 31:3-36:24, 38:4-50:22; Ex. 35.)

3. Advia-OG

Roche resorts to Advia-OG to try and fill holes in the Goffin-Meyvis document and SEG proposal. (Ex. 27, ¶¶ 23-24, 62, 64.) As explained in Section V.E.1, Advia-OG is dated March 2008, and did not exist at the time of September 2005 Goffin Meyvis letter or January 2006 SEG proposal. (Ex. 22 at BCID233031, -33.) BCI has no evidence that Imazu was aware of the Advia2120. In fact, Imazu testified [redacted]

[9] Ironically, Roche admitted that he quickly skimmed most of the SEG proposal and (with the aid of hindsight) focused on the pages that mention CSF body fluids. (Ex. 28, 119:9-121:5.)

[redacted] (Ex. 30, 130:25-131:9, 60:2-17, 64:3-12.) Similarly, BCI's Rule 30(b)(6) and other witnesses had no information about any Advia products. *See* Section V.E.

C. Legal Standard For Derivation

A person is not entitled to a patent if he did not himself invent the subject matter sought to be patented. 35 U.S.C. § 102(f). The inventors named on the issued patent are presumed to be correct, and the party alleging derivation must meet the heavy burden of proving derivation by clear and convincing evidence. *Cumberland Pharm. v. Mylan Institutional LLC*, 846 F.3d 1213, 1218 (Fed. Cir. 2017).

To show derivation, BCI must prove both (1) prior conception of the invention by another and (2) communication of that conception to the patentee. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1576 (Fed. Cir. 1997). Proof of prior conception requires more than a general goal or research plan; it requires a definite and permanent idea defined by the claims at issue. *Cumberland,* 846 F.3d at 1218. The requisite communication must be of the entire conception and must be sufficient to enable one of ordinary skill in the art to construct and successfully operate the invention. *Gambro,* 110 F.3d at 1577. Derivation is not proved by showing conception and communication of an idea that would make the claimed idea obvious. *Cumberland,* 846 F.3d at 1219; *Baxalta Inc. v. Bayer Healthcare LLC*, 513 F. Supp. 3d 426, 444-45 (D. Del. Jan. 19, 2021) (Andrews, J.).

D. BCI Lacks Clear and Convincing Evidence of Derivation

1. The Goffin Meyvis letter, SEG Proposal, and Advia-OG Are Hearsay

The Goffin Meyvis letter is an unauthenticated letter from a third-party. There is no evidence from anyone with first-hand knowledge of the document. This is classic hearsay, which is not admissible. Fed. R. Evid. 802. Further, to the extent that BCI relies on the summary in the Goffin Meyvis document (Ex. 26) of an unauthenticated poster presentation, BCI relies on hearsay

within hearsay. BCI cannot show that each part of the combined statements meets an exception to the rule against hearsay. *See* Fed. R. Evid. 805.

There is no evidence as to who authored the SEG proposal (Ex. 31). Even if it was an unknown employee of SEG, SEG is not a party. BCI cannot show that the SEG proposal qualifies as an opposing party's statement under Fed. R. Evid. 801(d)(2) or a business record exception under Fed. R. Evid. 803(6). Further, Roche relies on portions of the SEG proposal that were taken from unknown sources. Thus, BCI also relies on statements in the SEG proposal that are hearsay within hearsay.

Advia-OG (Ex. 22) is also an unauthenticated, hearsay document from a third-party. BCI cannot show that Advia-OG qualifies as a business record under Fed. R. Evid. 803(6).

BCI's derivation defense should be dismissed on summary judgment because it based on inadmissible hearsay. *Wi-Lan Inc. v. Sharp Elec. Corp.,* 362 F. Supp. 3d 226, 234 (D. Del. 2019), *aff'd*, 992 F.3d 1366, 1373-75 (Fed. Cir. 2021) (granting and affirming summary judgment because non-movant relied on inadmissible hearsay); *ABB Industrial Sys., Inc. v. Prime Tech., Inc.*, 120 F.3d 351, 357 (2d Cir. 1997) ("the reports would therefore be inadmissible at trial and cannot create a triable issue of fact"); *Arnold*, 826 F.2d at 1339 n.3 ("Summary judgment, of course, looks only to admissible evidence.").

2. The Goffin Meyvis letter is insufficient evidence of conception

BCI's expert admitted, in his deposition, that the Goffin Meyvis letter did not disclose all of the limitations of the Asserted Claims. (Ex. 28, 25:9-24.) For this additional reason, BCI's derivation claim should be dismissed. *Cumberland*, 846 F.3d at 1218 ("A conception must encompass all limitations of the claimed invention.").[10]

[10] Roche also admitted Imazu's earlier March 2005 Sysmex internal document (Ex. 29, App. F)

3. BCI does not have clear and convincing evidence that the inventors reviewed the Goffin Meyvis letter, SEG Proposal, or Advia-OG

BCI does not have anything approaching clear and convincing evidence that any named inventor received and reviewed the Goffin Meyvis document. The totality of BCI's evidence is that Imazu is listed in the "To" field of an email. However, Imazu [redacted]. The mere possibility that he may have received an email is not sufficient evidence of communication of a conception. *See Hedgewick v. Akers,* 497 F.2d 905, 908 (CCPA 1974) (access to files alone is insufficient to establish derivation); *Onyx Therap., Inc. v. Cipla Ltd.*, No. 16-988-LPS, 2020 WL 2214443, at *32 (D. Del. May 4, 2020) (mere possibility of receipt of a research plan is insufficient evidence of communication).

Likewise, BCI does not have anything approaching clear and convincing evidence that any named inventor received and reviewed the SEG proposal. Again, the totality of BCI's evidence is that Imazu is listed in the "To" field of an email. However, it is undisputed that [redacted] (Ex. 34 at SCorp-Del00334161.) Again, the mere possibility that Imazu may have received the SEG proposal in January 2006 is not sufficient evidence of communication of a conception. *See Hedgewick,* 497 F.2d at 908; *Onyx*, 2020 WL 2214443, at *32.

BCI has no evidence that any named inventor received the Advia-OG. Therefore, that document cannot serve as a basis for BCI's derivation defense. The Advia-OG also is not relevant

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disclosed the same concept as the September 2005 Goffin Meyvis letter. (Ex. 28, 182:17-184:14.) Thus, if the Goffin Meyvis letter (or SEG proposal) establish a conception, then Sysmex's earlier dated documents show an earlier conception than both the Goffin Meyvis document and the SEG Proposal which defeats BCI's derivation defense. (Ex. 29, ¶¶ 78-79, 82-86 and App. E-I; Ex. 35.)

as there is no evidence that it even existed prior to March 2008. (*See* Section V.E.1.) Further, to the extent BCI relies on the Advia-OG to fill in gaps in the Goffin Meyvis letter and SEG proposal, BCI improperly tries to show that the combination of these documents makes the claimed invention obvious, which is does not prove derivation. *Cumberland,* 846 F.3d at 1219; *Baxalta*, 513 F. Supp. 3d at 444-45.

BCI's derivation claim should be dismissed on summary judgment.

VII. BCI'S LACK OF ENABLEMENT DEFENSE SHOULD BE DISMISSED

In order to establish lack of enablement, BCI must show by clear and convincing evidence that a patent claim is not enabled when undue or unreasonable experimentation would have been necessary by one skilled in the art to make the invention based on the teachings of the specification. *Cephalon Inc. v. Watson Pharms, Inc.*, 707 F.3d 1330, 1336-37 (Fed. Cir. 2013). The Federal Circuit set forth a series of factors (called the *Wands* factors) to analyze whether undue experimentation is required including (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *Cephalon,* 707 F.3d at 1336. Conclusory and *ipse dixit* statements about undue experimentation are insufficient to meet the clear and convincing burden required to establish lack of enablement. *Cephalon,* 707 F.3d at 1338-39.

BCI has presented no evidence of undue experimentation. (Ex. 10 at 16-17.) Roche's opinions do not include a *Wands* analysis but instead include only conclusory, unsupported *ipse dixit* statements about undue experimentation. (Ex. 11, ¶¶ 150-154; Ex. 21, ¶ 49.) BCI's failure to provide clear and convincing evidence of undue experimentation warrants summary judgment

on BCI's enablement defense.[11] *Celotex*, 477 U.S. at 323-24; *Cephalon,* 707 F.3d at 1339-40.

VIII. SUMMARY JUDGMENT OF UNSUPPORTED ANTICIPATION DEFENSES

Sysmex asserts claims 1, 4, 9, 12, 18-21, 27 and 28 of the '350 patent and claims 1, 4, 6, 16, 17, 21 and 23-26 of the '351 patent. (D.I. 368.) However, BCI's expert, Roche, only offers the following opinions on anticipation:

- Claims 1, 7 and 11-15 of the '350 patent, and claims 1, 4, 5 and 6 of the '351 patent anticipated by the LH700 analyzer. (Ex. 11, ¶ 206.)
- Claims 1, 7 and 12-16 of the '350 patent are anticipated by the XE-2100 analyzer. (*Id.,* ¶ 211.)
- Claims 1, 7 and 11-15 of the '350 patent, and claims 1, 4, 5 and 6 of the '351 patent are anticipated by the Advia2120 analyzer. (*Id.,* ¶ 220.)

Roche confirmed in his deposition that he is not offering an opinion of anticipation for any other claims. (Ex. 36, 143:17-146:9.) Thus, BCI has no expert testimony relating to alleged anticipation of asserted claims 4, 9, 18-21, 27 and 28 of the '350 patent and asserted claims 16, 17, 21, and 23-26 of the '351 patent, and summary judgment that these claims are not anticipated is warranted. *See O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc*., 467 F.3d 1355, 1369 (Fed. Cir. 2006) (affirming district court's grant of summary judgment of where nonmovant "failed to timely provide evidence in support of that theory"); *Proveris*, 536 F.3d at 1267 (expert testimony was required to establish invalidity on grounds of anticipation and obviousness where the subject matter is sufficiently complex to fall beyond the grasp of an ordinary layperson).

[11] As explained in Section X.C, Roche's opinions in ¶¶ 150-154 of his Invalidity Report (Ex. 11) and ¶ 49 of his reply Invalidity Report (Ex. 21) should be stricken under *Daubert* for being conclusory and not based on any scientific analysis.

IX. SUMMARY JUDGMENT THAT THE XE-5000 AND XN PRODUCTS ARE COVERED BY THE CLAIMS IS APPROPRIATE

It is undisputed that claims 1, 3, 4, 7-12, 18-21, 27, and 28 of the '350 patent and claims 1, 4, 16, 17, 19, 21, and 24-27 of the '351 patent cover the XE-5000. (Ex. 37, ¶ 396; Ex. 38, ¶¶ 3-4, 10.) It is also undisputed that Sysmex's XN products are covered by claims 1, 3, 4, 7-12, 18-21, 27, and 28 of the '350 patent. (Ex. 37, ¶ 397.) BCI and its experts have not offered any evidence or opinions to the contrary. Therefore, summary judgment that the XE-5000 is covered by the above-identified claims of the '350 and '351 patent, and that the XN products are covered by the above-identified claims of the '350 patent, is warranted. *Donovan*, 661 F.3d at 185-88 (summary judgment is proper where expert testimony satisfies the movant's burden and is not contradicted by the nonmovant).

X. PORTIONS OF BCI'S EXPERT REPORTS SHOULD BE STRICKEN FOR FAILURE TO COMPLY WITH FRE 702 AND DAUBERT

BCI submitted expert reports from John Roche and Mitchell Rosen. Portions of these reports should be stricken for failure to comply with FRE 702 and the standards set forth in *Daubert v. Merrell Dow Pharms. Inc*., 509 U.S. 579 (1993).

A. Legal Standard

Federal Rule of Evidence 702 sets out the requirements for expert witness testimony:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The trial court has the "task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert,* 509 U.S. at 582, 597; *see also TQ Delta, LLC v. 2Wire, Inc.*, No. 13-1835-RGA, 2021 U.S. Dist. LEXIS 130971, at *2-3 (D. Del. July 14, 2021) ("the testimony must be reliable; it 'must be based on the "methods and procedures

of science" rather than on "subjective belief or unsupported speculation"; the expert must have "good grounds" for his o[r] her belief.'")

B. Roche's "Multi-mode detector" Written Description Opinion Should Be Stricken

Roche provides opinions regarding an alleged lack of written description for the "multi-mode detector" limitation in the Asserted Claims. (Ex. 11, ¶¶ 132-37.) In ¶ 136, Roche opines that the "specification does not disclose, nor did the inventors possess, a sample analyzer in which 'one or more multi-mode detectors' used in the body fluid mode do not include an optical detector to perform white blood cell classification using the DIFF measurement." However, none of the Asserted Claims include any such limitations. (D.I 368; Exs. 1-2 (claims).) For example, claim 1 of the '350 and '351 patents only requires "said multi-mode detector to sense cells in the introduced body fluid measurement sample"; they do not require a specific type of cell, like white blood cells, to be sensed and the "analyzing operation" limitation does not specify any classification of white blood cells. (Ex. 1, 17:10-15; Ex. 2, 17:40-49) Indeed, Roche admits: "There are no limitations in the remaining asserted claims as to how measuring of body fluid particularly for classifying white blood cells is accomplished." (Ex. 11, ¶ 133.) By Roche's own admission, his testimony is irrelevant to any issue and thus should be excluded. *In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999) (Rule 702 requires that expert testimony "'assist the trier of fact to understand the evidence or to determine a fact in issue.' This requirement is one of relevance and expert evidence which does not relate to an issue in the case is not helpful.")

Similarly, Roche ¶ 137 states that Plaintiffs "attempt to read the claims on BCI's electrical detectors, which classify white blood cells between mononuclear and poly-morphonuclear cells." But, as Roche admits, none of the Asserted Claims include limitations requiring cell classification in any particular way. (Ex. 11, ¶ 133; D.I 368; Exs. 1-2.) In fact, there is nothing in the Asserted

Claims reciting that detectors "classify" cells.[12] (*Id.*) It is irrelevant if the Accused Products have features in addition to those required by the claims. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 945 (Fed. Cir. 1990) ("The addition of features does not avoid infringement, if all the elements of the patent claims have been adopted.").

Because Roche's opinion is not tied to the limitations of the Asserted Claims, and takes positions that are irrelevant as a matter of law, ¶¶ 132-37 of the Roche Opening Report should be stricken as lacking a proper basis, unreliable, not tied to the Asserted Claims, and not helpful to the jury. *TMI*, 193 F.3d at 670.

C. Roche's Enablement Opinion Should be Stricken

The Roche Opening Report at ¶¶ 150-54 and the Roche Reply Report at ¶ 49 provide opinions regarding enablement that fail to address the *Wands* factors, which are discussed in Section VII above. Roche's opinions merely make the conclusory statement that the specification does not contain sufficient information "such that a POSA could make and use the claimed invention without undue experimentation." (Ex. 11, ¶ 153; Ex. 21, ¶ 49.) Roche does not identify "sufficient facts and data" as required by Rule 702 to support an opinion that any experimentation would be undue. His *ipse dixit* mention of "undue experimentation" is not based on any facts, data or scientific methods, and, therefore, will not assist the jury. *GE v. Joiner*, 522 U.S. 136, 146 (1997) ("nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").) For these reasons, ¶¶ 150-54 of Roche's Opening Report (Ex 11) and ¶ 49 of Roche's Reply Report (Ex. 21) should be stricken. *Id.*; *Neutrino Dev. Corp. v. Sonosite, Inc.*, 410 F. Supp. 2d 529, 540

[12] Roche cites no support for this opinion that detectors classify blood cells. The specification makes clear that electrical detector 42 and optical detector 41 generate signals when a blood cells passes through them, and the microcomputer 6 classifies the cells based on those signals. (Ex. 1, 8:20-29.)

& n.19 (S.D. Tex. 2006) (citing *Wands* and striking expert testimony of non-enablement for failure to apply proper standard); *Speedfit LLC v. Woodway USA, Inc.*, No.13-CV-1276 (KAM)(AKT), 2019 WL 1435911, at *8-9 (E.D.N.Y. Mar.29, 2019) (expert testimony precluded because it was conclusory and court was left guessing how much, if any experimentation was required and whether it was duly extensive).

D. Roche's Claim Construction and Indefiniteness Opinions on "Controller" Should Be Stricken

Roche's indefiniteness opinions are based BCI's means-plus-function claim construction arguments that were already rejected by the Court.[13] (Ex. 11, ¶¶ 155-57.) For example, Roche opines that the claim term "controller" does not refer to a "known class of structure." (*Id.*, ¶ 155.) The Court expressly rejected this argument, holding: "Therefore, the extrinsic evidence persuasively indicates that not only does "controller" refer to a known class of structures, but a POSITA would understand that the functions performed by the *claimed controller* are in line with those typically performed by a 'controller.'" (D.I. 230 at 11 (emphasis in original).) He opines that the claims set forth function without reciting sufficient structure to perform that function. (Ex. 11, ¶ 156.) The Court also rejected that argument: "For all of these reasons, BCI has not met its burden to demonstrate that the presumption against means-plus-function claiming has been overcome." (D.I. 230 at 13.) Roche also provides an opinion "in the event the Court adopts Beckman Coulter's construction of 'controller.'" (Ex. 11, ¶ 157.) The Court has not done so. (D.I. 230 at 5-13.) Roche's opinions should be stricken because they disregard the Court's construction of "controller." *See Sprint Commc'ns Co. v. Cox. Commc'ns Inc.*, 302 F. Supp. 3d

[13] BCI's counsel acknowledged during claim construction that indefiniteness issues were part of the claim construction. (Ex. 40, 20:12-17 (emphasis added).)

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597, 619-24 (D. Del. 2017) (expert opinions excluded as unreliable and unhelpful to finder of fact where inconsistent with claim construction).

Further, these opinions should be stricken because claim construction and indefiniteness are questions of law. *Au New Haven v. Ykk Corp.*, No. 15-CV-3411 (GHW)(SN), 2019 U.S. Dist. LEXIS 45044, at *18-19 (S.D.N.Y. Mar. 19, 2019) (Excluding expert's opinion "that the patent is invalid because it fails to meet the enablement and definiteness requirement of several nation's [including U.S.] patent laws" because that "testimony would improperly impede on the Court's function of instructing the jury on the applicable law."); *Advanced Tech. Incubator, Inc. v. Sharp Corp.*, No. 2:07-CV-468, 2009 U.S. Dist. LEXIS 109147, at *21-22 (E.D. Tex. Sep. 15, 2009) (striking expert's indefiniteness opinion because claim construction is a question of law and not proper for jury).). In addition, his conclusory opinions should be stricken because they do not disclose "sufficient facts and data" as required by Rule 702 to support an opinion that any Asserted Claim is indefinite, and, therefore, will not assist the jury.

E. Roche's non-infringement opinion re "multimode detector" should be stricken

The Roche Rebuttal Report at ¶¶ 33-38 provides an opinion of non-infringement based on the "multi-mode detector" limitation in the Asserted Claims. (Ex. 41.) [redacted] However, BCI never [redacted] asked the Court to construe the "multi-mode detector" limitation. (Ex. 43.)

In addition to concealing this defense during discovery, there are two other reasons to strike Roche's opinion. First, his opinion is based on comparing Sysmex's XN product, which is covered by the '350 patent, to BCI's accused DxH products. (Ex. 41, ¶¶ 34-36.) It is legal error to compare

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the accused products to the patentee's product. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) ("Infringement, literal or by equivalence, is determined by comparing an accused product not with a preferred embodiment described in the specification, or with a commercialized embodiment of the patentee, but with the properly and previously construed claims in suit."). Therefore, Roche's opinions comparing the patentee's product and BCI's Accused Products lack a sufficient basis, and are unreliable, irrelevant, and likely to confuse, rather than assist, the jury.

Second, Roche's Rebuttal Report also attempts to change the claim language for the "multi-mode detector" limitation. In ¶ 38, he correctly recites the claim language "multi-mode detector[] configured to operate in both the blood measuring mode and the body fluid measuring mode." (Ex. 41.) However, in the next sentence, he tries to change the wording of the limitation to "detectors . . . configured to operate *differently*." (*Id*., ¶ 38 (emphasis added).) Roche's attempt to offer an opinion based on his addition of "differently" to the claim language is impermissible and requires exclusion. *Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, No. 15-819-LPS-CJB, 2018 WL 1785033, at *5 (D. Del. Apr. 4, 2018) (excluding non-infringement testimony for being unreliable and unhelpful because the non-infringement testimony introduced an extra claim limitation).

F. Roche's non-infringement opinion re '350 claim 21 should be stricken

The Roche Rebuttal Report at ¶¶ 43-47 is directed to the term "each configured to electrically or optically sense cells" in claim 21 of the '350 patent. (Ex. 41.) This is a brand new defense [redacted]. In addition, in ¶ 44, Roche states: "A POSA would understand the plain language of this claim limitation to mean that each detector *is capable of* being configured to sense cells either electrically or optically." (*Id.* (emphasis added).) BCI never proposed a construction for the claim term "each configured to electrically or optically sense

cells," and Roche's attempt to add "is capable of" to the claim is improper and should be excluded. (Ex. 43.) *Integra,* 2018 WL 1785033, at *5.

In ¶ 46, Roche states: "I further question the veracity of Dr. Madisetti's claim . . . ." (Ex. 41.) This sentence should be struck as it is improper for one witness to opine on the veracity of another witness. *ART+COM Innovationpool GmbH v. Google Inc.*, 155 F. Supp. 3d 489, 510 (D. Del. 2016) (Andrews, J.) (technical expert "is not, however, an expert on [declarant's] state of mind, and therefore cannot opine on whether [declarant] was lying or mistaken when he authored his declaration.").

G. Roche's Patentable Subject Matter Opinion Should Be Stricken

The Roche Opening Report at ¶¶ 277-91 provides opinions regarding subject matter eligibility under 35 U.S.C. § 101. (Ex. 11.) In ¶ 280, Roche states:

> [I]t is my opinion that a person of ordinary skill in the art would understand that Claim 1 of the '350 patent is directed to an abstract idea. In particular, Claim 1 of the '350 patent is directed to the idea of collecting and analyzing data regarding blood and body fluid and displaying results in two different modes.

(*Id.*) This opinion is inadmissible, and should be stricken, for several reasons.

First, patent eligibility under § 101 is a question of law that may contain underlying issues of fact. *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1367 (Fed. Cir. 2020). Expert testimony relating to subject matter eligibility is only helpful and allowed when "it is limited to supplying background facts about the nature of the art and the patents." *Metaswitch Networks Ltd. v. Genband US LLC*, No. 2:14-cv-744-JRG-RSP, 2016 U.S. Dist. LEXIS 28234, at *6-7 (E.D. Tex. Mar. 5, 2016). Roche's opinion that claim 1 of the '350 patent is directed to an abstract idea is an impermissible opinion on a question of law. *Id.*; *see also W.L. Gore & Assocs. v. C.R. Bard, Inc.*, No.11-515-LPS-CJB, 2015 U.S. Dist. LEXIS 197368, at *13-14 (D. Del. Nov. 20, 2015) (expert testimony regarding legal conclusions is not permissible).

Second, the first step in the § 101 analysis is to consider the claims in their entirety, and in light of the specification, to ascertain whether as a whole they are directed to an abstract idea. *CardioNet,* 955 F.3d at 1367-68. Roche fails to apply the proper analysis. For example, he fails to consider claim 1 in its entirety. Instead, he simplifies claim 1 of the '350 patent as reciting a "'sample analyzer' with 'a plurality of detectors' and a 'controller.'" (Ex. 11, ¶ 287.) But claim 1 includes much more. For example, Roche overlooks that the language of claim 1 describes a particular type of sample analyzer with a plurality of detectors to sense cells in blood samples and in samples of certain types of body fluids. (Ex. 1, 16:40-48.) The '350 patent explains that these types of body fluids have a much lower number of cells to detect than blood. (*Id.*, 1:30-31.) The claim also requires that a controller is programmed to selectively operate the sample analyzer in a blood measuring mode or in a body fluid measuring mode, in which the sensing operation in the body fluid mode is different from the sensing operation in the blood measuring mode. (*Id.* at 16:49-65.) Roche does not address this claim language. His failure to conduct an analysis using appropriate methodology warrants exclusion. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 155-57 (1999) ("district courts must 'scrutinize' whether the 'principles and methods' employed by an expert 'have been properly applied to the facts of the case'").

Finally, Roche only makes passing reference to the remaining Asserted Claims in the '350 and '351 patents. (Ex. 11, ¶¶ 288-91.) He does not address any specific claim limitations in the other Asserted Claims, such as "perform the analyzing operation in the blood measuring mode" and "perform the analyzing operation in the body fluid mode" (Ex. 1, 18:51-53, 18:63-65 (claim 12)), "automatically initiating pre-washing said multi-mode detector" (*id.*, 19:64-65 (claim 19)), or "count mono-nucleated and poly-nucleated cells" (*id.*, 20:31-32 (claim 20); Ex. 2, 22:53-55 (claim 24)). Roche commits legal error by treating claim 1 of the '350 patent as

representative of all the Asserted Claims. *See Berkheimer v. HP Inc.*, 881 F.3d 1360, 1365-66, (Fed. Cir. 2018) ("A claim is not representative simply because it is an independent claim."). Roche's opinions on all other Asserted Claims should be stricken as lacking a sufficient basis.

H. Roche's Materiality Opinions Should Be Stricken

The Roche Opening Report at ¶¶ 292-308 (Ex. 11), Reply Report at ¶¶ 135-38 (Ex. 21), Supplemental Report at ¶¶ 59-70 (Ex. 27), and Supplemental Reply Report at ¶¶ 83-86 (Ex. 32) provide opinions regarding materiality of documents allegedly not disclosed to the PTO during prosecution of the of the Asserted Patents. Roche's opinions include his speculation as to the state of mind of the examiner. For example, Roche's Opening Report provides opinions regarding what "the patent examiner was aware of" (Ex. 11, ¶ 296) and whether the Asserted Patents would have issued "had the patent examiner been aware of" certain references (*id.*, ¶ 297). Similarly, the Roche Reply Report speculates that "[there] is no reason to believe the examiner would have been aware of [certain references]" and what is purportedly "an important question that would have been relevant to the examination of the patent applications" that issued as the Asserted Patents." (Ex. 21, ¶ 136.) Roche's Reply Report further speculates about what the examiner was aware of. (*Id.*, ¶ 138.) The Roche Supplemental Report and Supplemental Reply Report speculate that "the examiner could not have accepted that the different sensing limitation imparted patentable significance to the claim and the Advia 120/Advia 2120 is prior art to the claims of the Asserted Patents." (Ex. 27, ¶ 70; Ex. 32, ¶ 84.) Roche admitted that he is not a patent attorney, and not an expert qualified to opine in the field of patent law. (Ex. 36, 39:1-23; *see also* Ex. 11, ¶¶ 1-17; Ex. 11 at App. A.)

The law in this Court is clear that experts cannot testify regarding materiality of prior art or "opine on how the Patent Office would have acted in certain circumstances." *PureWick Corp. v. Sage Prod., LLC*, No. CV 19-1508 (MN), 2021 WL 2593338, at *1-2 & n.6 (D. Del. June 24,

2021); *Brigham & Women's Hosp. Inc.*, No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010) ("The law of this district is clear that experts in patent cases may not opine on whether a party engaged in inequitable conduct, discuss whether certain information was *material to a pending patent application*, or otherwise provide legal conclusions on substantive issues of patent law." (emphasis added)); *W.L. Gore*, 2015 U.S. Dist. LEXIS 197368, at *13-14. Accordingly, Roche's Opening Report ¶¶ 292-308, Reply Report ¶¶ 135-38, Supplemental Report ¶¶ 59-70, and Supplemental Reply Report ¶¶ 83-86 should be stricken. (*Id.*; Exs. 11, 21, 27, 32.)

I. Roche's opinions re legal conclusions and other litigation should be stricken

The Roche Opening Report at ¶ 217 attempts to opine improperly on the law: "It is my understanding that the mere automation of a previously known process is not a patentable distinction." (Ex. 11.) This statement should be stricken as an improper legal opinion. *PureWick*, 2021 WL 2593338, at *1-2 (the court "is responsible for instructing the jury on the relevant law").

The Roche Rebuttal Report at ¶¶ 24-25 and 27-28 offers commentary on other litigation between Sysmex and BCI.[14] (Ex. 41.) These paragraphs should be stricken as irrelevant and outside the scope of Roche's expertise. *TMI*, 193 F.3d at 670; *see also TC Tech. LLC v. Sprint Corp.*, No.1:16-cv-00153-RGA, 2019 U.S. Dist. LEXIS 180262, at *7 (D. Del. Oct. 18, 2019) (Andrews, J.) (excluding testimony about patents not in the case and other litigation because it "will serve only to confuse the issues, mislead the jury, and use up extremely limited trial time.").

The Roche Rebuttal Report at ¶ 26 states that "the Examiner confirmed his understanding" and "Sysmex acquiesced in the understanding of the Patent Examiner." (Ex. 41.) These opinions about the state of mind of the examiner and Sysmex should be dismissed as irrelevant, speculation

[14] ¶¶ 23 and 26-27 of Roche's Rebuttal (Ex. 41) also should be stricken for the additional reasons that they offer opinions on patents that have not been asserted in this case, and therefore are not relevant and will not assist the jury. *TMI*, 193 F.3d at 670; *TC Tech.*, 2019 U.S. Dist. LEXIS 180262, at *7.

that will not assist the jury. *Brigham*, 2010 WL 3907490, at *2 ("parties are generally not permitted to explain patent prosecution histories through expert testimony"); *ART+COM*, 155 F. Supp. 3d at 510 (technical expert cannot opine on state of mind).

J. Roche's Commentary On Imazu's Veracity and "Summaries" Of Imazu's Testimony Should Be Stricken

Roche's Supplemental Report contains sections entitled "Mr. Imazu's Testimony Regarding DDX 173" and "Mr. Imazu's Testimony Regarding DDX 176". (Ex. 27, ¶¶ 10-25 and 26-39.) These paragraphs and others include occasional references to Imazu's testimony such as "Mr. Imazu did not deny . . ." (*id.*, ¶¶ 11, 26), Imazu could not "recall any details" (*id.*, ¶¶ 47, 55), as well as attacks on Imazu's credibility for not remembering details of events from 15 years ago (*id.*, ¶¶ 8 ("Mr. Imazu should have been able to answer questions about basic scientific concepts in his deposition"), 65 (same), 21-22 ("he purportedly did not remember"), 37 (same), 56 ("unable to point to any documents")). Many of these statements are repeated in Roche's Supplemental Reply Report. (Ex. 32, ¶¶ 15, 25-26, 46-49.) Roche's commentary on another witness's state of mind and testimony is improper, and should be stricken. *ART+COM*, 155 F. Supp. 3d at 510. In addition to opining on Imazu's veracity and what Imazu should and should not know, ¶¶ 8, 11, 21, 22, 26, 37, 47, 55, 56 and 65 as well as every limitation in Roche's claim charts (*see e.g.*, Ex. 27, at Roche's Exs. 1-3) purport to provide summaries of Imazu's deposition testimony. (Ex. 27.) Roche's summaries are inappropriate expert testimony. *Wi-Lan*, 992 F.3d at 1375 (expert cannot be used as conduit for hearsay; "the appropriate way to adduce factual details of specific past events is, where possible, through persons who witnessed those events."); *ART+COM*, 155 F. Supp. 3d at 510.

Sysmex Objects to BCI's Redactions.

K. Roche's Conception Opinions Should Be Stricken For Refusing To Answer Questions Regarding The Bases for the Opinions

Roche's Supplemental Report and Supplemental Reply Report provide opinions that the Goffin Meyvis letter and SEG proposal disclose a conception of the claimed inventions of the Asserted Patents. (Ex. 27, ¶¶ 44, 47-57; Ex. 32, ¶¶ 8, 14, 24.) To prove derivation, each document must communicate the complete claimed invention. *Cumberland*, 846 F.3d at 1218. [redacted]

L. Rosen's Opinions That Are Not Based On The Asserted Claims Should Be Stricken

The Court should exclude Mr. Rosen's damages opinions at ¶¶ 15, 47, 50, 61, 89, 95, 99, 101-107, 111, 119, 123, 143-146, 149, 151-152, 156-158, 160-162, 164, 166, 188 and 189 of his expert report (Ex. 44) that are based on his erroneous understanding that the "patented feature" of the '350 and '351 patent claims "is the automation of a cleaning cycle or auto wash performed prior to or in between body fluid analyses within a hematology analyzer and also relates to the counting and displaying results related to tests associated with mononucleated cells and polynucleated cells." (Ex. 45, 115:14-116:22, 118:15-119:5, 136:9-137:20, 138:12-139:1, 203:23-

Sysmex Objects to BCI's Redactions.

204:23.)[15] Rosen's opinions based on his understanding of the "patented feature" of the claims are unreliable because they are not based on "good grounds" and would not assist the trier of fact. Specifically, ***none*** of the 20 Asserted Claims include limitations corresponding to the full "patented feature" that forms the basis for many of Rosen's opinions.[16] (*See* Ex. 46.)[17] Thus, Rosen's damages opinions are based on his incorrect premise that all the claims require the "patented feature," as exemplified in ¶ 47 of his report as follows:

> 47. I understand that the alleged value of the claims of the Patents-in-suit generally lies in the automation of a cleaning cycle ("autowash") performed prior to, or in between, body fluid analyses within a hematology analyzer. I further understand that certain claims also relate to counting and displaying results related to tests associated with mononucleated ("MN") cells and polynucleated ("PMN") cells. . . .

(Ex. 44, ¶ 47; *see also id.*, ¶ 102.)

The fact that none of the Asserted Claims include Rosen's "patented feature" makes his opinions based on his erroneous understanding of the claims unreliable, and unhelpful and confusing to jury. *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1324-25 (Fed. Cir. 2014) ("Proof of damages must be carefully tied to the claimed invention itself."). Thus, his opinions that depend on his erroneous understanding of the "patented feature" should be excluded. *Id.* at 1324-25 (excluding an expert's damage testimony because the expert relied on another expert testimony which does not tie to the claimed invention).

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[15] Rosen used other terms in his report as synonyms for "patented feature" such as "accused functionality," "patented functionality," "accused feature," and "accused functionalities." (Ex. 45, 139:13-140:6, 141:3-142:15.)

[16] Independent claims 1 and 12 of the '350 patent, and independent claim 1 and dependent claim 4 of the '351 patent do not include any limitations that constitute the "patented feature." Eleven of the 20 Asserted Claims do not include an "autowash" limitation, and thirteen of the 20 Asserted Claims do not include a limitation for measuring and displaying mononucleated and polynucleated cells. (*See* Ex. 46 (chart with claims and limitations).)

[17] Exhibit 47 [redacted]

Sysmex Objects to BCI's Redactions.

[redacted] Roche's testimony is exactly opposite of what Rosen says that he relied on. Thus, Rosen's reliance on an erroneous characterization of Roche's position is another ground to exclude Rosen's opinions. *Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc.*, 55 F. Supp. 2d 1024, 1032, 1039–40 (N.D. Cal. 1999) (excluding expert opinion contradicted by scientific fact and by the party's other expert) (citing *General Electric Co. v. Joiner*, 522 U.S. 136 (1997)); *EZ Dock, Inc. v. Schafer Sys., Inc.*, No. CIV.98-2364(RHK/AJB), 2003 WL 1610781, at *4–6 (D. Minn. Mar. 8, 2003) (excluding expert testimony for the lack of factual basis because the testifying expert relied on another expert's opinion that there were only two suppliers in the market when in fact there were at least four suppliers).

Accordingly, Rosen's opinions in paragraphs 15, 47, 50, 61, 89, 95, 99, 101-107, 111, 119, 123, 143-146, 149, 151-152, 156-158, 160-162, 164, 166, 188 and 189 of his expert report (Ex. 44) should be excluded. (*See* Ex. 47.)

M. Rosen's Opinion on Non-Asserted Patents Should Be Precluded

In ¶ 104, Rosen opines about the scope of various other Sysmex patents and that "Sysmex could have asserted any of these patents against Beckman as early as 2008." (Ex. 44, ¶ 104.) Rosen's opinion should be precluded because he is admittedly unqualified to provide the opinion and has no basis for his opinion. [redacted]

[redacted]

Sysmex Objects to BCI's Redactions.

[redacted] Courts routinely preclude testimony from unqualified experts such as Rosen. *M2M Sols. LLC v. Motorola Sols., Inc.*, No. 12-33-RGA, 2016 WL 767900, at *3-4, *6 (D. Del. Feb. 25, 2016) (holding that the expert is not qualified to characterize the claimed invention because the expert only has "little more than a rudimentary understanding of the invention").

XI. CONCLUSION

Sysmex respectfully requests that the Court grant its motion for summary judgment and excluding opinions under *Daubert* on all grounds addressed above.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 30, 2021, true and correct copies of the foregoing document were caused to be served on the following counsel of record as indicated:

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